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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,292	02/23/2006	Pratibhash Chattopadhyay	FER-14669.001.001	6373
7609	7590	03/15/2011	EXAMINER	
RANKIN, HILL & CLARK LLP 23755 Lorain Road - Suite 200 North Olmsted, OH 44070-2224			HAGOPIAN, CASEY SHEA	
			ART UNIT	PAPER NUMBER
			1617	
			MAIL DATE	DELIVERY MODE
			03/15/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/541,292	CHATTOPADHYAY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	CASEY S. HAGOPIAN	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 December 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16, 19 and 20 is/are pending in the application.  
 4a) Of the above claim(s) 9-16 and 20 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-8 and 19 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                             |                                                                   |
|-------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                 | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|                                                                                                             | 6) <input type="checkbox"/> Other: _____ .                        |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Amendment/Remarks, Declaration under 37 CFR 1.132 and Terminal Disclaimers filed 12/3/2010.

No claims have been amended or newly added. Claims 17-18 were previously cancelled. Accordingly, claims 1-16 and 19-20 remain pending in the application. Claims 9-16 and 20 stand withdrawn from further consideration, without traverse. Claims 1-8 and 19 are currently under examination.

#### ***Terminal Disclaimer***

The terminal disclaimers filed on 12/3/2010 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration dates of 6,998,051 and 7,083,748 have been reviewed and are accepted. The terminal disclaimers have been recorded.

### **WITHDRAWN REJECTIONS**

Applicant's amendment renders the rejection(s) under 35 USC 102 over 6,998,051 moot. Specifically, the Declaration under 37 CFR 1.132 filed 12/3/2010 is sufficient to overcome the rejection under 35 USC 102 based upon 6,998,051. Thus, said rejection has been overcome and accordingly, withdrawn.

Applicant's amendment renders the Double Patenting rejections over 6,998,051 and 7,083,748 moot. Specifically, applicant filed Terminal Disclaimers that have been reviewed and accepted. Accordingly, said Double Patenting rejections are withdrawn.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### **NEW REJECTIONS**

After further consideration, the following rejections have been newly added:

##### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Castor et al. (USPN 5,776,486, hereinafter referred to as "Castor").

Castor teaches methods of making liposomes containing hydrophobic drugs, with critical, supercritical or near critical (SCoCoNC) fluids by combining a phospholipid, a drug and an aqueous phase with a SCoCoNC fluid and upon reduction in pressure, liposomes are formed (abstract).

Regarding instant claims 1, 7 and 19, in a particular embodiment, a mixture of drug, phospholipid and a SCoCoNC fluid is injected through a tip or orifice into an aqueous phase (i.e. water which reads on polar solvent), the mixture is decompressed and liposomes are formed (col. 6, lines 2-15). It is noted that "melt" is defined by the specification as a mixture of "a polymer, a wax and/or a lipid, optionally, an active agent and a supercritical fluid. Thus, while Castor does not explicitly recite the term "melt", Castor reads on the limitation as it is defined. Similarly, Castor does not recite the term "emulsion" however, Castor teaches the claimed method steps and ingredients and as such implicitly teaches the resulting "emulsion".

Regarding instant claim 2, Castor teaches using a nozzle at a temperature of 60 °C (col. 24, lines 16-17).

Regarding instant claim 3, Castor teaches that liposomes are collected in a vessel (col. 9, lines 26-35).

Regarding instant claim 4, Castor teaches cleaning procedures after liposome formation including using compressed air (col. 11, lines 23-31).

Regarding instant claim 5, Castor teaches a control means for the rate of decompression which thereby allows control of the size of liposomes (col. 6, lines 63-65).

Regarding instant claim 6, Castor teaches the particular SCoCoNC fluid, carbon dioxide (col. 6, lines 17-19).

Thus, the teachings of Castor render the instant claims anticipated.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Castor et al. (USPN 5,776,486, hereinafter referred to as "Castor") in view of Needham et al. (USPN 6,143,321, hereinafter referred to as "Needham").

Castor teaches the elements discussed above.

Castor is silent to the addition of a surfactant.

Surfactants and their properties are well known in the art, particularly in liposome formation. Needham teaches the use of surfactant in the formation of liposomes containing active agents in order to increase the amount of active agent that the liposome can hold (col. 3, lines 26-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a surfactant in the process of producing liposomes advanced by Castor with a reasonable expectation of success because Needham teaches surfactants effectively increase the amount of active agent a liposome can contain.

Thus, the combined teachings of Castor and Needham render the instant claim obvious.

### ***Conclusion***

All claims have been rejected; no claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi, can be reached at 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Casey S Hagopian/  
Examiner, Art Unit 1617

/Carlos A. Azpuru/

Primary Examiner, Art Unit 1617